v7

Sterigenics

October 6, 2015

Donald M. Smith
6EN-AS
U.S. Environmental Protection Agency
Region 6
Compliance Assurance and Enforcement Division
1445 Ross Avenue, Suite 1200
Dallas, Texas 75202

Dear Mr. Smith:

This letter is in response to the email you sent to Mr. Steve Ortiz, the General Manager of Sterigenics Santa Teresa facility on September 24, 2015. Following are the responses to the questions regarding the ethylene oxide (EO) release at the Santa Teresa facility on September 14, 2015.

1. **Provide the name, title, email, phone number and mailing address for the person to whom correspondence should be sent regarding the release.**
   Kathleen Hoffman
   Sr. Vice President – Global EH&S
   2015 Spring Road, Suite 650
   Oak Brook, IL 60523
   630-928-1758
   Khoffman@sterigenics.com

2. **Who owns and/or operates the location where the event occurred?**
   Sterigenics U.S., LLC

3. **Briefly describe the facility, e.g. discuss what activities take place on-site and what substances are produced, processed, handled or stored on-site.**
   This facility performs batch sterilization of medical products and bioburden reduction of spice products using ethylene oxide (EO). On occasion, propylene oxide (PO) is used to treat various nut products. EO is stored in 400-pound cylinders. The maximum quantity of EO at this facility is 20,000 pounds or 50 cylinders. The medical supplies and/or spices are placed in the sterilization chambers on pallets where the EO is introduced. Upon completion of the sterilization cycle, EO is removed from the sterilization chamber and routed to an emission control system, which destroys the EO. The pallets are then removed from the sterilization chambers and placed in an aeration room. The aeration room is a high-temperature with continuous air-flow environment that allows the treated product to off-gas residual EO. The emissions from the aeration room are routed to a catalytic oxidizer for destruction.

Sterigenics International, LLC
2015 Spring Road, Suite #650 □ Oak Brook, IL 60523
Tel 630.928.1700 □ Fax 630.928.1701 □ www.sterigenics.com

4. **What process units or equipment were involved in the event? Provide a brief description and process flow diagram for the processes involved.**
   Sterilization Chamber #2 was involved in the incident. For further information, please refer to the attached process flow diagram.

5. **At the time of the incident, was the facility operating under a Title V Air Permit?**
   This facility operates under state permit No. 0733-M15-R1 issued by the New Mexico Air Quality Bureau. The facility does not meet the applicability criteria for a Title V permit and thus was not issued a Title V permit by the permitting agency.

6. **What is the SIC or NAICS code for the facility where the event occurred?**
   The facility's SIC code is 7389 and NAICS code is 561910.

7. **Did the event take place at a Risk Management Program covered process?**
   Yes, the process is covered by the Risk Management Program.

8. **Provide a detailed description and timeline of the event. Include the best known start time and duration of the incident and the timeline for any emergency response.**
   The release was caused by the Chamber #2 door hand wheels not being tightened sufficiently during the sterilization cycle. This caused the EO to escape the chamber and activated local Lower Explosive Limit (LEL) alarms. The plant was evacuated in response to the LEL alarms. After building evacuation, responding facility employees donned proper personal protective equipment (PPE) and re-entered the facility to investigate. The chamber door wheels were tightened to stop the leak and EO concentrations returned to safe levels. The release began at approximately 7:40 am and ended around 8:10 am PST. The duration of the incident was approximately 30 minutes.

9. **What specific substances were released during the event, including the estimated or known amounts of each substance? Include all air contaminants that were released during the event, even those materials with release amounts below the reportable quantity.**
   We estimate that about 37 pounds of EO vapor was released inside the facility from Sterilization Chamber #2. The facility has exhaust fans that vent indoor air directly to atmosphere from the roof. In addition, Chamber #2 is located adjacent to the aeration room which has a negative pressure and draws some air from the chamber room into the aeration room. The aeration room is controlled by a catalytic oxidizer with a minimum control efficiency of 99%. We estimate approximately 10% of the EO released during this event, or about 4 pounds, vented through the aeration room and catalytic oxidizer. Therefore, the total EO released to the atmosphere would be 0.04 pounds via the catalytic oxidizer and 33 pounds to the outside environment via the exhaust fans.

10. **Have there been any investigations or audits of the event? Are investigations or audits pending? Who performed the investigations or audits? Provide a copy of the reports, audits, or any other analysis describing the causes and consequences of the event, including all draft reports and/or draft audit results.**
Sterigenics has conducted an internal investigation into the EO release event. The internal investigation of this event included Operations, Global EH&S, Global Engineering, and SteriPro Lab. A copy of the initial EO release report is included. A more detailed investigation report with corrective actions is also being developed.

11. **What is the initial best known cause or root cause of the event? Were there any additional contributing factors that you are aware of?**
The root cause for this EO release was the Chamber 2 door hand wheels not being tightened sufficiently during the sterilization cycle. A key contributing factor was that this sterilization cycle operated under positive-pressure conditions during the injection of EO into the chamber. Another contributing factor is that this positive pressure cycle was being operated in sterilization chambers with manual doors.

12. **What measures have been taken to address the findings, conclusions or recommendations of the investigations or audits?**
As an immediate corrective action taken within 30 minutes of the incident occurring, the chamber door wheels were tightened to stop the leak and EO concentrations returned to safe levels. Based on our investigation, the following list of additional corrective actions and expected completion dates:
    - Review incident with all facility employees and response to incident to identify any areas for improvement - Complete
    - Review incident and investigation with all Sterigenics locations – October 30, 2015
    - Limit the operation of this cycle to chambers with automated doors and gaskets to ensure doors are properly locked until further controls, described below, are implemented on applicable manual chambers – Complete
    - Install equipment to implement chamber door hand wheel tightening notification system for manual chambers – Complete
    - Implement tracking log system where two operators confirm and verify the tightening of the manual doors – Complete
    - Review safety concerns with customer and see what they can do to minimize the product sterilized with the positive-pressure cycle and confirm a timeline for the elimination of this cycle – October 9, 2015
    - Modify leak or emergency procedures to immediately estimate release amount for all events that trigger an LEL alarm – December 30, 2015
    - Inventory all positive-pressure sterilization cycles and perform risk assessment – October 30, 2015

- Conduct EO Release emergency drills on all shifts at Santa Teresa facility – November 30, 2015

13. **Are there any findings, conclusions, or recommendations that have not been addressed fully, and if so, what measures remain to be taken, and what is the expected timeline for implementing those measures?**
See #12 for corrective actions and expected date of completion.

14. **Were there any fatalities or injuries attributed to the event? If yes, explain.**
No fatalities or injuries occurred during this event.

15. **Did you, or anyone else, issue any evacuation, road closure, or shelter-in-place orders as a result of the event for your facility or surrounding community? If yes, explain.**
According to Sterigenics Global EH&S procedures, the facility is required to evacuate the building upon an LEL alarm greater than 25%. A 30% LEL alarm occurred and activated the building evacuation notification system. Therefore, all facility employees evacuated. No evacuations, road closures, or shelter-in-place order were issued for the community.

16. **Was there any property or equipment damage, both on-site and/or off-site, that resulted from the event? If yes, explain.**
No, there was no property or equipment damage that resulted from the event.

17. **What emergency response measures were taken, by you or anyone else, to stop and/or to minimize hazards from the event?**
As stated above, the facility responded to the LEL alarms by evacuating the building. LEL alarms above 25% also interlock all chamber controls and put them in a cycle stop or hold status as a safety control. Accordingly, all production was immediately suspended. After facility responders donned appropriate PPE, they re-entered the facility to investigate. The chamber door wheels were tightened to stop the leak and EO concentrations returned to safe levels.

18. **Did you or anyone else the facility perform any air monitoring during or after the event, including any routine monitoring? If so, then please provide a summary of the results.**
The Chamber #2 area is continuously monitored by strategically placed LEL detectors which alarm at 10% of the LEL (3,000ppm) or higher. There is also a Gas Chromatograph area monitor port in the vicinity which detects low level concentration of EO for worker protection. During the event, LEL alarms greater than 25% activated a facility evacuation.

19. **Identify and provide copies of any industry standards, internal standards, SOPs, or manufacturer's recommendations related to the incident including equipment, process units, and personnel activities involved in the incident.**
Sterigenics has a number of standard operating procedures for the operation of its sterilization equipment and its environmental, health and safety procedures. In addition, the facility and its process equipment is built to applicable industry standards. One specific internal standard applicable to this EO release event is the Emergency Operating Procedure for High level EO Alarms (EOP-050). Attached is a copy of this procedure.

20. **Please provide any documents associated with the identification of hazards at your facility related to the incident.**
Sterigenics has a number of risk assessment tools that are used to identify hazards associated with our process and operations. We have an EHS procedure "Hazard Identification – Risk Assessment" (EHS-201) that outlines all such risk assessments. Attached is a copy of this procedure. One critical risk assessment is the Process Hazard Analysis (PHA) for the EO process at the Santa Teresa facility. This is completed and updated within our Process Safety Management and Risk Management Program. To better understand the specific hazards associated with ethylene oxide, also attached is the ethylene oxide Safety Data Sheet.

21. **Has any local, state, or federal agency conducted an investigation or requested information regarding the event? If so, please provide the name and contact information for each agency person who conducted an inspection or requested information.**
Per emergency notification requirements in 40 CFR 302.6 and 40 CFR 355.40, upon discovering the potential release was likely greater than the 10-pound reportable quantity and in accordance with notification requirements in 40 CFR §302.6 and 40 CFR §355.40, facility personnel immediately notified the following agencies of the release:
    - National Response Center (NRC) (Case # 1128845)
    - Dona Ana County/Las Cruces LEPC, and
    - New Mexico State Emergency Response Commission (SERC)

    In addition, we submitted a follow up letter in accordance with 40 CFR §355.40 to Mr. David Almaguer of the Dona Ana County/Las Cruces LEPC and Ms. Susan Walker and Mr. Henry Jolly of the NM SERC. We have not received notice of any investigation that has been conducted. A copy of the follow up letter is attached for your reference.

If you have any questions regarding this letter or our investigation please contact Kathy Hoffman (see contact information in #1) or me at 630-928-1771 or kwagner@sterigenics.com

Sincerely,

Kevin Wagner
Director, EH&S

cc: Steve Ortiz – General Manager
Juan Segovia – Vice President Operations
Kathy Hoffman – Sr. Vice President – EH&S

Encl.

Attachment 1: Process Flow Diagram

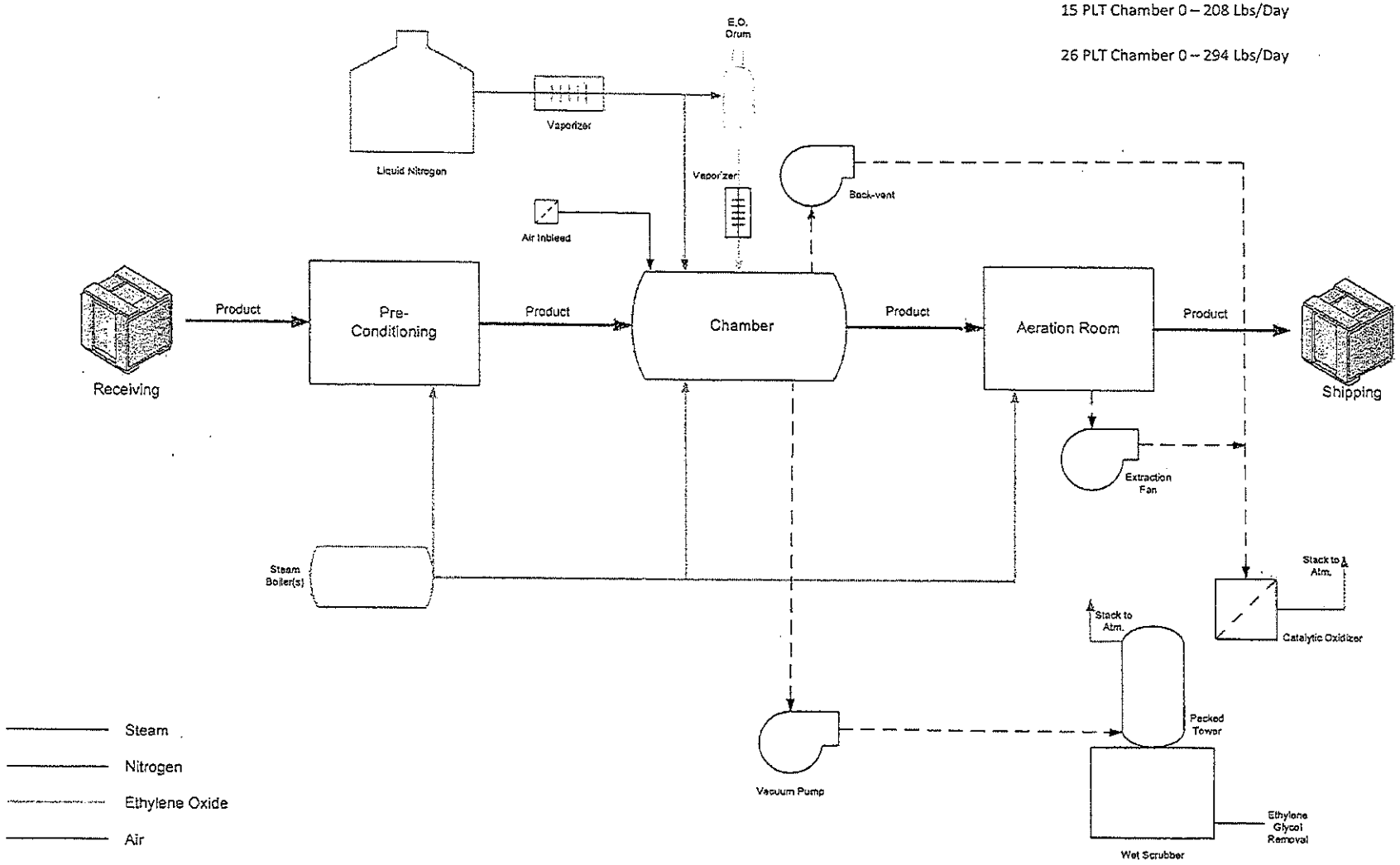
Sterigenics Proc_ss Flow Diagram

13 PLT Chambers 0 – 126 Lbs/Day

30 PLT Chambers 0 – 371 Lbs/Day

15 PLT Chamber 0 – 208 Lbs/Day

26 PLT Chamber 0 – 294 Lbs/Day



Attachment 2: Initial EO Release Report

Sterigenics

SPILL AND RELEASE INVESTIGATION REPORT

NOTE: COMPLETE THIS FORM WHENEVER THERE IS A SPILL OR RELEASE OF A HAZARDOUS SUBSTANCE INCLUDING ETHYLENE OXIDE

A. Facility Originating Report

Facility: Santa Teresa	**Phone:** 575-589-9300
Address: 2400 Airport Rd	**City/State/Prov.:** Santa Teresa, NM 88008

B. Incident Description

1. **Date/Time**

Start Date: 14-Sep-2015	**End Date: 14-Sept-2015**	
Start Time: 7:42 am	**End Time: 8:08 am**	**Total Time: 00:26 min**

2. **Environmental Conditions** (check all that apply)

Location of Spill/Release: Chamber 1 and 2 vault	
Spill/Release onto or into: ☒ Air ☐ Ground ☐ Water	**Release Occurred:** ☒ Indoors ☐ Outdoors
Weather type: ☐ Overcast ☒ Sunny ☐ Precipitation	**Wind Direction and Speed:** SSE at 8.1 mph

3. **Substance Description:**

Name of Substance Spilled/Released: Ethylene Oxide	
Amount(s) Spilled/Released: Undetermined	**Amount Recovered:** TBD
Extremely Hazardous Substance? ☒ Yes ☐ No	**Reportable Quantity of Substance:** 10 lbs
Source Container: Sterilization Chamber 2	**Capacity of Container:** 13 Pallet Chamber
Brief Description of Incident: During processing in Ch.2, in Gas Inject A, the door hand wheels on rear door were not tightened sufficiently. This caused EtO to escape the Chamber into Chamber Module Room and activated a 30% LEL alarm.	
Corrective Actions Taken: Plant evacuated and Facility Employees first responders donned PPE and re-entered the facility and tightened door wheels to mitigate the leak.	

C. Notifications

Entity Notified	Phone No.	Time/Date of notification	Person notified
Corporate EHS	630-928-1700	Approx: 8am 14 Sep 15	Juan Segovia
National Resp Center	800-424-8802	3:45 pm 18 Sep 2015	Operator on Duty
Office of Emerg/Mgmt	575-647-7900	3:48pm 18 Sep 2015	David Almaguer
NM Emergency Response Comm	505-476-0617	3:50pm 18 Sep 2015	Henry Jolly/ Left Voicemail

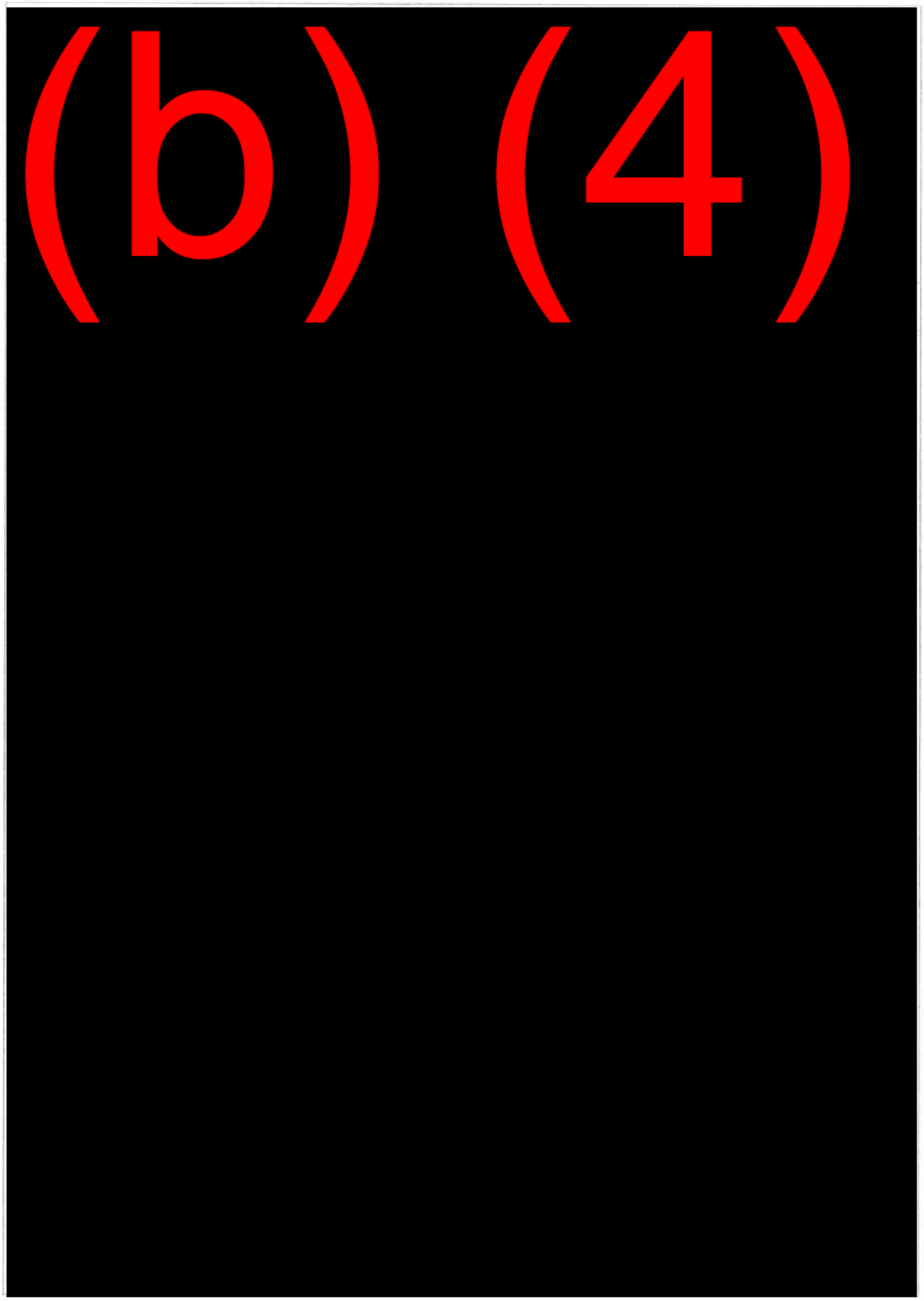
D. Review and Approval

	Print Name	Signature	Date
Spill Report Prepared by	Stephen Ortiz		21 Sep 15
Facility (General) Manager	Stephen Ortiz		21 Sep 15

Attachment 3: Emergency Operating Procedure for High EO Level Alarms

(EOP-050)

(b) (4)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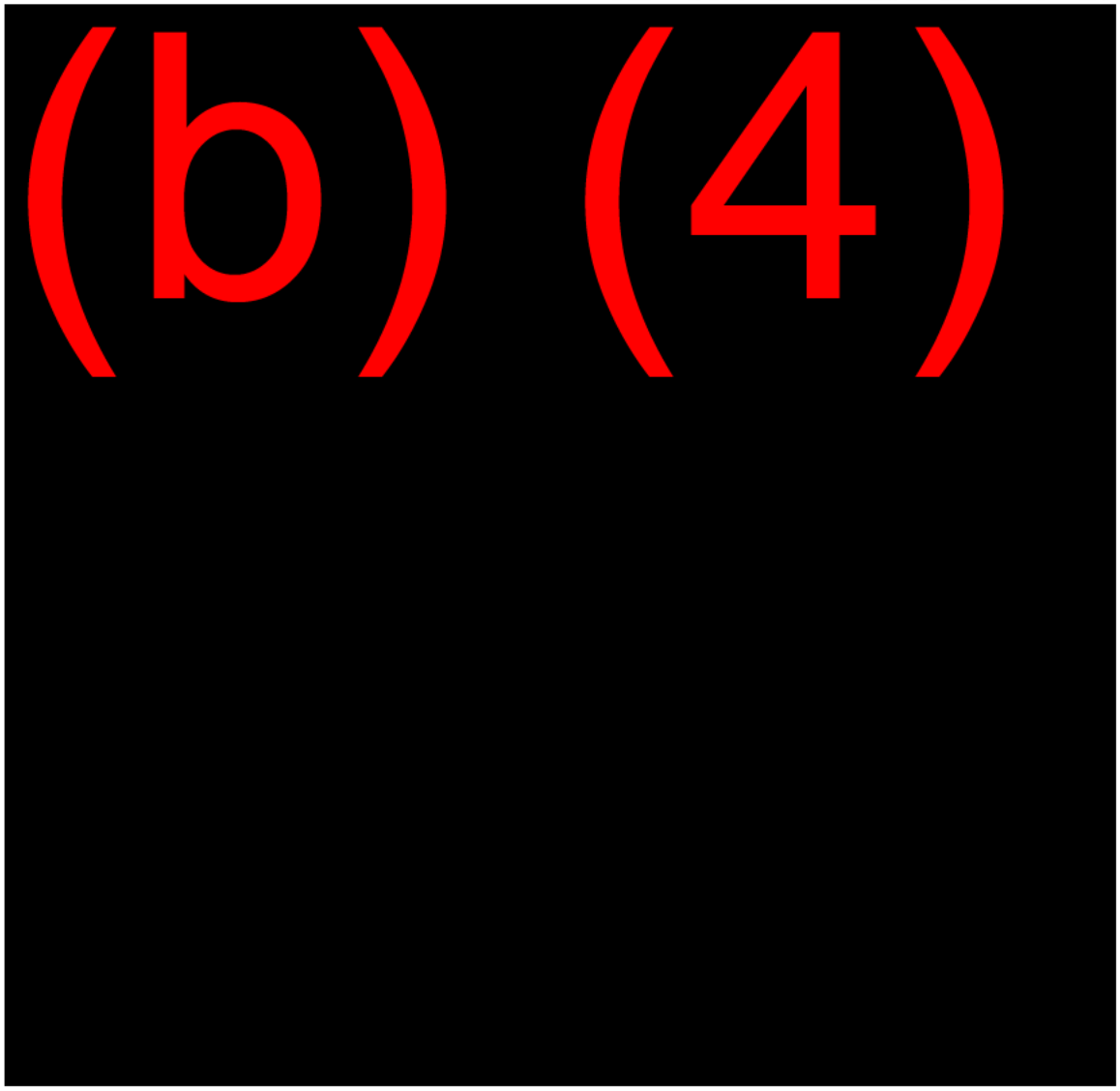
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Attachment 4: Risk Assessment Procedure

EHS-201

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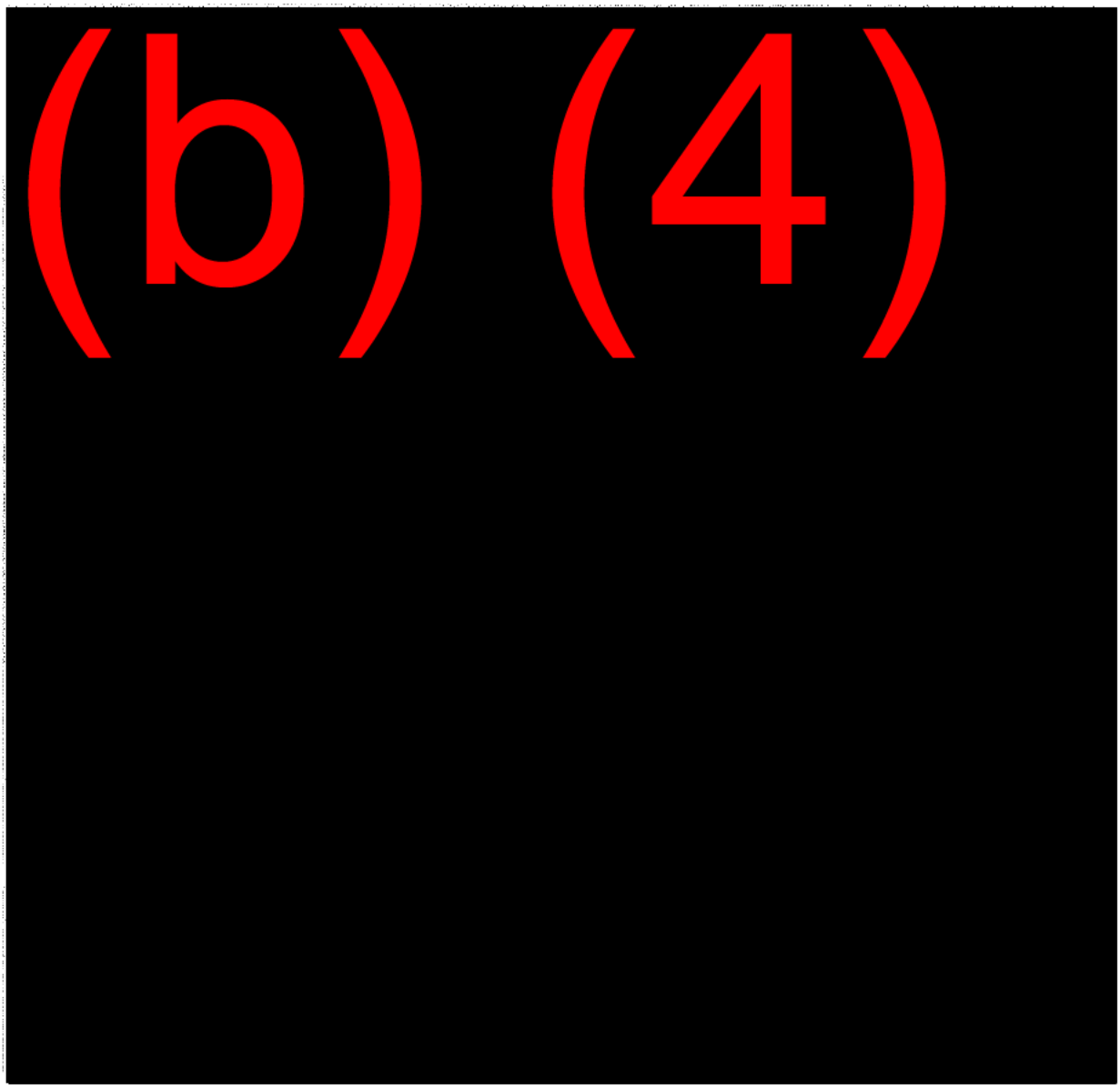
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Submit Action Report | Spill Summary Report

NATIONAL RESPONSE CENTER 1-800-424-8802
GOVERNMENT USE ONLYGOVERNMENT USE ONLY***
Information released to a third party shall comply with any
applicable federal and/or state Freedom of Information and Privacy Laws

Incident Report # 1128845

INCIDENT DESCRIPTION

*Report taken by: MST3 ANNALIESE ENNIS at 17:35 on 18-SEP-15
Incident Type: FIXED
Incident Cause: OPERATOR ERROR
Affected Area:
Incident occurred on 14-SEP-15 at 07:47 local incident time.
Affected Medium: AIR ATMOSPHERE

REPORTING PARTY

Name: STEPHEN ORTIZ
Organization: STERIGENICS LLC

CHICAGO, IL

PRIMARY Phone: (575)5899300
Type of Organization: PRIVATE ENTERPRISE

SUSPECTED RESPONSIBLE PARTY

Name: STEPHEN ORTIZ
Organization: STERIGENICS LLC

CHICAGO, IL
PRIMARY Phone: (575)5899300
Type of Organization: PRIVATE ENTERPRISE

INCIDENT LOCATION

2400 AIRPORT RD County: DONA ANA

City: SANTA TERESA State: NM

RELEASED MATERIAL(S)

CHRIS Code: EPM Official Material Name: ETHYLENE OXIDE (30% OR LESS), PR
Also Known As:
Qty Released: 0 UNKNOWN AMOUNT

DESCRIPTION OF INCIDENT

CALLER IS REPORTING A RELEASE OF ETHYLENE OXIDE INTO THE ATMOSPHERE FROM A STERILIZER AT THE FACILITY DUE TO OPERATOR ERROR.

INCIDENT DETAILS

Package: NO
Building ID:
Type of Fixed Object: OTHER
Power Generating Facility: NO
Generating Capacity:
Type of Fuel:
NPDES:
NPDES Compliance: UNKNOWN

IMPACT

Fire Involved: NO Fire Extinguished: UNKNOWN

INJURIES:	NO	Hospitalized:	Empl/Crew:	Passenger:
FATALITIES:	NO	Empl/Crew:	Passenger:	Occupant:

EVACUATIONS: YES 20 Who Evacuated: EMPLOYEES Radius/Area:

Damages: NO

Closure Type	Description of Closure	Hours Closed	Direction of Closure
Air: N			
Road: N			
Waterway: N			
Track: N			

Major Artery: N

Passengers Transferred: NO
Environmental Impact: UNKNOWN
Media Interest: NONE Community Impact due to Material:

REMEDIAL ACTIONS

PPE WAS DONNED AND DISCOVERED THE SOURCE AND SECURED IT.
Release Secured: YES
Release Rate:
Estimated Release Duration:

WEATHER

Weather: CLEAR, □F

ADDITIONAL AGENCIES NOTIFIED

Federal:
State/Local:
State/Local On Scene:
State Agency Number:

NOTIFICATIONS BY NRC

CENTERS FOR DISEASE CONTROL (GRASP)
18-SEP-15 17:42 (770)4887100
NATIONAL COMMUNICATIONS CENTER (COMMAND CENTER U.S. INCIDENTS)
18-SEP-15 17:42 (555)1111111
COLORADO INFO ANALYSIS CENTER (FUSION CENTER)
18-SEP-15 17:42 (720)8526705
DOT CRISIS MANAGEMENT CENTER (MAIN OFFICE)
18-SEP-15 17:42 (202)3661863
EL PASO POLICE DEPARTMENT (INTELL/ORGANIZED CRIME)
18-SEP-15 17:42 (915)6806522
EPA OEM (MEXICAN INCIDENTS)
18-SEP-15 17:42 (202)5643850
U.S. EPA VI (MAIN OFFICE)
18-SEP-15 17:43 (866)3727745 MARTIN
USCG NATIONAL COMMAND CENTER (MAIN OFFICE)
18-SEP-15 17:42 (202)3722100
COATEA / JRT (MAIN OFFICE U.S. BORDER INCIDENTS)
18-SEP-15 17:42
NATIONAL INFRASTRUCTURE COORD CTR (MAIN OFFICE)
18-SEP-15 17:42 (202)2829201
NOAA RPTS FOR NM (MAIN OFFICE)
18-SEP-15 17:42 (206)5264911
NATIONAL RESPONSE CENTER HQ (MAIN OFFICE)
18-SEP-15 17:42
NATIONAL RESPONSE CENTER HQ (AUTOMATIC REPORTS)
18-SEP-15 17:42 (202)2671136
NTSB PIPELINE (MAIN OFFICE)
18-SEP-15 17:42 (202)3146293
OCCUPATIONAL SAFETY & HEALTH ADMIN (DALLAS OFFICE)
18-SEP-15 17:42 (801)9180995
TCEQ (MAIN OFFICE)
18-SEP-15 17:42 (512)2392507
USCG DISTRICT 8 (MAIN OFFICE)
18-SEP-15 17:42 (504)5896225

ADDITIONAL INFORMATION

*** END INCIDENT REPORT # 1128845 ***

Report any problems by calling 1-800-424-8802
PLEASE VISIT OUR WEB SITE AT http://www.nrc.uscg.mil

Close Window